UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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USA EX REL KESTER, et al.,

Plaintiffs,

v. 11 CV 8196

NOVARTIS PHARMACEUTICALS CORP.,

Defendant.

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November 4, 2014
10:15 a.m.

Before:

HON. JAMES C. FRANCIS,

Magistrate Judge

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THE DEPUTY CLERK: All rise.

THE COURT: Good morning. Please be seated.

(case called)

MR. ROSS: Good morning, your Honor, Li Yu for the Federal Government.

THE COURT: Good morning.

MS. MARTIN: Good morning. Rebecca Martin for the United States.

MR. MILLER: Good morning. Chris Miller for the State of New York.

MR. ROSS: Good morning, your Honor, Steve Ross on behalf of California.

THE COURT: Good morning.

MS. SHETH: Good morning, your Honor, Manisha Sheth on behalf of Novartis.

MS. SKAISTIS: Your Honor, Rachel Skaistis also on behalf of Novartis.

MR. MAYELL: Your Honor, Manvin Mayell for Novartis as well.

THE COURT: Good morning.

And I understand that we have a number of other parties represented on the phone. I will not ask for your appearances. I have them here, and we certainly welcome your participation, and ask that when you participate, you identify yourselves before you speak so that we have an accurate record.

So thank you all for attending. I'm looking forward to being illuminated on this, and why don't we start with Novartis.

Ms. Sheth.

MS. SHETH: Thank you, your Honor. May I approach the podium?

THE COURT: Please.

MS. SHETH: Good morning, your Honor.

We, as you know, your Honor, Novartis has moved to compel two specific categories of documents. The first are what we will refer to as adherence documents, and the second are what we will refer to as treatment and therapy protocol documents.

There was a third category of documents that was originally included in our motion. These were the settlement communications related to the stipulation and facts with BioScrip. Shortly after Novartis filed our motion to compel, the government, including the states, have produced documents related to that third topic. So that is no longer at issue in the motion.

Let me begin by just reiterating the broad standard of relevance which governs Novartis's motion. Under Rule 26(b), a party is entitled to discovery on any matter that is relevant to a party's claim or defenses. And the courts in this court have construed Rule 26(b) very broadly to encompass any matter

that bears on or that reasonably could lead to other matter that could bear on any issue that is or may be in the case.

Now, the discovery that Novartis seeks here, both categories, are relevant to a critical issue in the case; whether Novartis violated the antikickback statute. And as we will go through both categories, we'll see exactly how those documents are relevant to that central issue in the case.

Now let's start with the medication adherence and treatment protocols. There is medication adherence programs. As a preliminary matter, there is no dispute in this case that the government itself believes that adherence is a good thing. An effective adherence program improves patient care, improves patient outcomes, and avoids adverse health consequences. Moreover, it reduces healthcare cost. In fact, the cost of medication not adherence were estimated to exceed over $177 billion in the year 2000. So there is no question that the government thinks adherence programs are a good thing, and that the government itself encourages medication adherence by promoting programs such as refill reminders and by encouraging adherence initiatives. For example, the CMS Star Ratings Program is administered by CMS and provides financial incentives to Medicare Part D sponsors in the form of quality bonus payments that are based on a number of metrics, one of which is the adherence rate among patients.

So what documents is Novartis seeking on this topic?

There are basically four categories of documents that we are seeking. The first --

THE COURT: Before you get there, I think I want to stop at the threshold for a second.

I understand the false claim to be that Novartis receives kickbacks for, among other things, encouraging adherence. And if I understand the antikickback statute correctly, there is essentially a safe harbor for receiving kickbacks or payments, if you will, provided that there is disclosure made; that is, provided that there's transparency, then there's no liability under the Act.

If that's correct, why do we care about adherence, the Government's position with respect to adherence? Isn't the issue simply whether the proper disclosures were made?

MS. SHETH: Actually, your Honor, we would argue the Government's theory is that there is a false claims violation based on a predicate violation of the antikickback statute.

THE COURT: Right.

MS. SHETH: And their theory is that Novartis offered remuneration in exchange for a referral. So Novartis is offering rebates, discounts which, as your Honor notes, are protected under the safe harbor. And also they argue that Novartis did patient allocations or offered patient allocations to specialty pharmacies such as BioScrip in this case, to encourage the promotion or recommendations of Novartis's

product, in this case Exjade. So those two elements, the recommendation and the remuneration are at issue in this case. And the government has alleged that refill programs, or adherence programs more specifically, are improper recommendations. Because what Novartis was doing, along with BioScrip, was doing programs that were geared not towards patient education and counselling, but rather were geared towards simply pushing their, Novartis's product, Exjade onto patients. And the issues that are relevant with regard to the Government's own programs will shed light on what does the government think is an appropriate adherence program. So that discovery will shed light on the contours of what the government views as an appropriate adherence program.

THE COURT: So your view is that the Government's theory is not merely that Novartis is failing to disclose its program, but that its program is substantively illegal.

MS. SHETH: Correct. And that is their theory, and that is throughout their complaint. What they're alleging with regard to BioScrip is that Novartis induced BioScrip to act as an agent of Novartis; so basically an agent of Novartis's sales force. And so the communications and the discovery about the Government's program will show three important characteristics of what the government thinks is an appropriate adherence program. The first is the scope of appropriate communications with the patient. The second is what does the government think

about qualifications and training of the personnel who are employed to administer the adherence program, and the third, what are appropriate incentives that should be given to entities or personnel who are administering adherence programs, including what is the appropriate metric for measuring adherence.

So these are, these three components of an adherence program are directly put into play by the Government's own allegations in this case. And what they've alleged with regard to patient communications is that the communications between BioScrip personnel and patients were based on clinical pretext. They were not accurately conveying information to the patients about the medications, about side effects. One of the central allegations in the Government's complaint is that BioScrip misled patients by unduly emphasizing the need to take Exjade, in terms of complying with the doctor's orders, versus understating the risks in terms of side effects that are present. And they told -- the allegation is that they told patients to ignore the side effects and continue taking Exjade and to take Exjade as long as possible.

THE COURT: I understand that those are the Government's allegations in the complaint.

I'm having trouble, and perhaps you're not the person I should be asking, about linking those allegations to particular legal claims.

MS. SHETH: Right. And I think those allegations would go to the element of the antikickback statute that relates to whether or not this was a recommendation. And if we look at the 1994 fraud alert, for example, which is cited by Judge McMahon in her decision on the motion to dismiss, one of the factors that's considered in that guidance is whether or not the communication was genuine patient counselling or education or was it more akin to what they call, quote unquote, sales-oriented patient counselling and education. And I think that is a central issue as to whether or not what Novartis was doing here was encouraging a recommendation or merely encouraging patients to take medication that's already been prescribed by their physicians; can that be a recommendation? All they're doing is having patients take medication that's already prescribed by a physician pursuant to a valid prescription.

Now, the second thing that the government alleges in its complaint which ties back to what the government views as appropriate adherence is the qualifications of the personnel who are administering the adherence program. So throughout their complaint the government alleges that BioScrip personnel were not qualified; that they did not have the appropriate training in the disease state of iron overload; that they were not trained on Exjade as a medication, and because they were not trained they should not have been making these patient

outreach calls.

Now, what the government does with regard to either its own adherence programs or private programs that it views as good and appropriate adherence programs, is relevant because it goes to what are those qualifications that are necessary, what are those training requirements that are necessary and appropriate to administer an adherence program.

And then the third category goes to the incentives; what are appropriate incentives that should be offered to an individual or entity who is encouraging adherence. And we know that the government itself does encourage making incentives or making payments to individuals for encouraging adherence. And in this case the allegation is that Novartis offered incentives in the form of rebates, discounts and allocations, patient allocations to encourage adherence. So the question is is that an improper -- the legal question under the AKS is is that a proper incentive -- is that an improper inducement or is it a proper incentive. And so Novartis's position is that what it did in terms of patient communications, its training of BioScrip both with regard to the disease state and the medication at issue here, was all proper, and the incentives it offered to BioScrip were proper. And we believe that the discovery relating to the government programs will confirm and will show that those programs support Novartis's argument, as opposed to the Government's argument, which is that the conduct

was improper and constituted a violation of the antikickback statute.

Now, what is the Government's position in response to Novartis's relevance argument? Well, I think we should start with the states. Because the states do recognize that this discovery is relevant in part, because the states have agreed to produce a limited subset of these adherence documents that relate specifically to Exjade and that are in the possession of the single state agency. So the state implicitly, or at least in part, concedes the relevance. And they, despite making that agreement, however, they have to date failed to produce any such adherence documents. So we're still waiting for those.

But I want to point out that the states' limitations on those two topics are inappropriate. First, their limitation to just adherence documents that relate to Exjade is too limiting. Because whether or not a particular practice, such as providing financial incentives to encourage adherence, whether or not that violates the antikickback statute doesn't depend on the drug in question. Those parameters of what constitutes an appropriate adherence program in terms of patient communication, incentives, what's the appropriate metric to measure adherence, all that isn't going to be drug specific or disease state specific. And so programs that relate to diabetes drugs or hypertension drugs, the metrics that are used, the communications that are deemed proper, the

qualifications that are deemed appropriate, all that will be relevant to informing the fact finder's view that Novartis's conduct here was entirely appropriate and not within the parameters of the antikickback statute.

THE COURT: And if you're wishing to go that far afield, are you prepared to pay for it?

MS. SHETH: Pardon?

THE COURT: Are you prepared to pay for it, for the government to do the search that would obtain that information with respect to every drug?

MS. SHETH: Well, I have to -- I'd have to raise that issue with our client.

I mean, generally, the rule is that the government, you know, as a party in this litigation would bear the cost of their own discovery. I mean, we would argue that it is not terribly burdensome, and that's going to the burdensome argument.

The federal government has already produced documents from other agencies, including CMS and HHS and OIG and the FDA. And so we're not asking the government to search every government agency. I mean, it is limited in two ways; one, with regard to the agencies that would have policy making -- health policy making jurisdiction with regard to adherence programs; and, second, to a limited subset of documents that relate to the Government's views on adherence and the sort of

adequacy and the efficacy of those programs.

THE COURT: Do you have any reason to believe that the Government's general adherence policies differ drug to drug?

MS. SHETH: We don't know. I mean, there's very limited information available in the public domain. And what we've been able to find so far relates to, primarily, two programs. One was the CMS Star Ratings Program and the second was the Medication Management and Adherence Therapy Programs. And both of these, from what we can tell, appear to be pretty general. I don't believe that the policies vary from -- based on disease state or by drug. But generally I think they do pertain generally to the concept of why medication adherence is a good thing and what are the scope and parameters of those programs.

The other category of documents that we are looking for, which is actually an important category, is documents that relate to whether or not adherence communications are excluded from marketing communications. And so part of Novartis's request pertain to rules and guidance that the government has put out that excludes those type of communications from marketing communications. And although the government is saying no those are not relevant because they are strictly in the context of HPPA and privacy concerns, we do think it is relevant to one of the central issues in this case, which is are what -- is what Novartis doing in this case in terms of

encouraging adherence, encouraging patients to take Exjade as prescribed by their physicians, is that truly marketing activity, as referred to in 1994 fraud alert, or is it more akin to patient education and counselling? And so that, again, is informative to that underlying issue which is in dispute.

The second issue which the states limit their production to is documents that are within -- documents that reflect the states' own adherence programs. And they're refusing to produce documents that reflect the states' views about private adherence programs. And for the same reasons we articulated earlier, the relevance of the documents is the same; whether the state is sponsoring the adherence program or whether the state is making a pronouncement on an adherence program that's offered by a private entity.

Now, with regard to the United States Attorney's Office, generally they make two arguments against the relevance of these documents.

First, they argue that the antikickback statute doesn't apply to the government. And I think, your Honor, we don't need to address that issue. I mean that is issue is irrelevant. Because what we are looking for -- we're not making the argument that the fact that the conduct by the government is not covered by the antikickback statute means that it shouldn't be covered for Novartis. To the contrary, we're arguing that what the government says about adherence,

how it administers its own adherence programs is relevant to Novartis's claim that its conduct here was entirely appropriate. And so what the government says is appropriate about those three things, patient communications, qualifications and training of folks who are administering the adherence programs and incentives and metrics to measure adherence are entirely what is necessary to look at, whether or not Novartis's conduct here violated the antikickback statute. We say it doesn't, government says it does, and those documents will help inform that decision.

The second argument that the federal government makes in opposition is that unless Novartis knew about or relied upon these documents in creating its own adherence program, they're not relevant. And, again, that takes -- that position takes a very limited view of relevance. Because under the Government's view, those documents are only relevant to Novartis's intent, and we are arguing that it's much broader than that. It goes to the heart of what is at dispute in this case, whether or not Novartis violated the antikickback statute.

Now the second category of documents that we are seeking are the treatment protocols and therapy documents. And these primarily relate to three different topics. The first are documents relating to the Government's views about clinical considerations related to immunosuppressive therapy for kidney transplant patients. So it's a very limited category of

documents pertaining to a very specific therapy for a very specific patient population; second, are documents relating to iron chelation therapy for patients at government hospitals; and then third is actually a response to interrogatory that relates to identifying the health care professionals at government hospitals who are responsible for making prescribing decisions for immunosuppressive therapy.

Now why are these documents relevant? The government has really called into question whether the communication that Novartis was providing to the SPs and the SPs were providing to the physicians was clinically appropriate and accurate, or was it supported or was it simply pretext in an effort to encourage doctors to switch patients from CellCept to Myfortic. CellCept is the competitor drug to Myfortic.

Second, they argue with regard to the Exjade scheme that the information that was provided to patients was not clinically supported and was not accurate and, rather, was just done under the guise of encouraging marketing of Exjade and putting as many patients on Exjade and continuing them to take Exjade for an extended period of time without regard to clinical considerations, including whether it was medically appropriate or medically necessary.

So in light of those allegations by the government that what Novartis and what the SPs were doing was simply clinical pretext, these documents are relevant to showing what

does the government think? What do government hospitals, what do the healthcare providers at those hospitals think about the clinical benefits of Myfortic? What do they think about Exjade?

Now, with regard to the Government's complaint, it's actually the fourth step. They have a multi step scheme outlined in their complaint as to Myfortic. And the fourth and critical step in their alleged scheme is that Novartis induced specialty pharmacies to improperly influence physicians by providing them with pretextual clinical reasons to switch from CellCept to Myfortic.

Now, what Novartis is arguing is that the information that was provided was clinically appropriate. And what we expect to see is that doctors switched patients from CellCept to Myfortic for a variety of clinically supportive reasons, one of which was the fact that Myfortic had an enterate coating which enabled -- which led to fewer GI complications or fewer GI side effects in patients. In contrast, CellCept, because of the way that it was metabolized in the body, led to greater GI side effects; second, that there is a known drug-to-drug interaction between CellCept and proton-pump inhibitors, and patients who are taking proton-pump inhibitors had reduced efficacy when they were taking CellCept. So the proton-pump inhibitor led to a reduction in efficacy when taking CellCept. This often results in patients taking less of the dose that

they were supposed to take, led to further GI side effects, and actually even presented problems with adherence to the medication as prescribed by their physicians.

And then the third reason, the third clinically supported reason is that some physicians believed that in the context of transplant patients, that it is better to have a branded product instead of a generic product for two reasons; one, bioequivalence concerns. You could have a generic that has a certain window of bioequivalence, and given that window, it's better to have a known branded product rather than a generic product.

And then the second reason was pill confusion. If there's multiple forms of a generic, patients may get confused because of the appearance of their pill looks different, and that may lead to complications in terms of failing to adhere to their medication.

So these are the three reasons that were given by the SPs and the physicians when they are -- that were relied upon by those individuals when making healthcare decisions for their patients. And the government is claiming those were simply pretext and they were not clinically supported. And the documents that we are seeking will help show for the Myfortic patients that these actually were valid reasons, and the government itself at its own hospitals viewed these reasons as clinically supported.

THE COURT: Well, are we talking about the adequacy of these reasons generally; that is, that it's true in general that there are fewer GI complications with Myfortic, or are we talking about the communications made with respect to a particular patient?

MS. SHETH: No, and that's a very good question, your Honor. We're not looking for individual patient specific communications. And I would agree that would encompass a much broader universe of documents.

But what we are looking for are the treatment and protocol documents. And what I mean by that is that each hospital will have a treatment protocol; that this is the guidance that's used by the hospital and provided to the physicians at that hospital for how do we treat generally immunosuppressive -- how do we treat kidney transplant patients with immunosuppressive agents. They could be broad and they could say, we generally use immunosuppressive therapy following a kidney transplant; it should be maintained X days after the kidney transplant. They could be even more specific. They could say we start with CellCept as the treatment of choice. If the patient experiences GI side effects, we then go to Myfortic. So it's really a guidance document that is provided at hospitals for its healthcare providers on how to treat patients. Of course healthcare providers have the discretion to make deviations from that general guidance document, but it

shows the overall preference in terms of treatment by that particular hospital. And what we are seeking are the treatment protocols in place at government hospitals.

THE COURT: Why isn't that a subject of expert testimony; that is I would think you would have an expert who would say this is perfectly appropriate and here's why.

MS. SHETH: It may be the subject of expert testimony, but that expert testimony will certainly carry more weight if the expert is allowed to have the benefit of those documents that the government itself -- I mean, we have a government who is claiming that Novartis's reasons here were clinical pretext. But if the government itself at its own hospitals views these same reasons; the better GI profile, the PPI interaction, the preference for branded medication for kidney transplant patients -- if the government itself believes that there's appropriate reasons to use Myfortic or appropriate reasons to switch a patient from CellCept or generic CellCept to Myfortic, that's certainly relevant to Novartis's defense that these were appropriate clinical reasons.

THE COURT: Have you had any discussions with the government about doing a sample in order to obtain either these particular documents or others on your list?

MS. SHETH: We have not. We've really hit a roadblock in our meet and confer discussion on the topic of relevance. And so the topic of burden, we've not really been able to make

much progress on. Because once we, you know, have this dispute that between the parties as to whether or not the documents are relevant, we're not really getting to that meet and confer dialogue about, well, are there limited places, certain VA hospitals that we can go to; are there regional centers that perhaps have the authority to implement at the more local VA hospitals. So I mean I agree with your Honor that there may be ways that we can work with the government on its burden objection, but I think we first need a threshold determination on relevance.

THE COURT: Well, not necessarily. I'm not sure there is a brightline between relevance and burden. And if you're sufficiently cooperative with respect to burden, they might be more inclined to waive a relevance argument, at least at this stage.

MS. SHETH: Yeah, and again we are -- I mean, we are willing to work with them. Just the discussions to date have not been productive on that front. We hadn't received any proposals for how to narrow the scope of the discovery.

So for the same reasons that the Myfortic treatment documents are relevant, it's a very similar argument with regard to the Exjade documents and the documents that relate to iron chelation therapy.

Now, in this context the iron chelation therapy documents are relevant to showing what is the appropriate

patient population that should get Exjade to treat iron overload; what is the appropriate iron level in patients' blood that would warrant taking Exjade; how long should the patients stay on Exjade; how should it be administered; should it be administered on an as-needed basis as the government alleges or should it be administered continuously pursuant to a valid prescription by a physician? So these are all issues that again would be in the treatment protocol documents relating to iron chelation therapy at government hospitals. And again this is put into dispute by the Government's own complaints. If you look at the Government's complaint, they describe the Exjade refill, the Exjade scheme as a refill scheme. Basically, they're saying that the specialty pharmacies completely abdicated their clinical judgment and just were simply pushing Exjade on patients with regard -- without regard to whether it was clinically appropriate or medically necessary, and they're pushing patients on Exjade who don't need it. And, worse, they're alleging that the specialty pharmacies are putting patients on Exjade despite a doctor saying, okay, you're experiencing XYZ side effects, I'm going to take you off Exjade. So these are all questions or allegation that the government has really put into play when they're describing the scheme in this case. And the discovery relating to the iron chelation therapy documents will reflect the Government's views about what is appropriate and what's an appropriate clinical

reason to put a patient and continue a patient on Exjade.

Now, the government relies heavily on Judge McMahon's decision on the motion to dismiss to argue that these documents are not relevant. But it's important to remember two things about that decision. First, it was on a very narrow legal issue relating to the sufficiency of the Government's allegations with regard to the causation element. So it's a specific element under the False Claims Act that was at issue in those motions.

And, second, and perhaps most importantly, that motion was on a motion to dismiss, and the Court was bound to accept the allegations in the complaint as true. And the key allegation which the Judge accepted as true was that there was a kickback, that there was a violation of the antikickback statute. So that part of the motion to dismiss was just accepted as true because it was a motion to dismiss. And here we are arguing that this requested discovery on both fronts, the adherence documents, as well as the transplant -- excuse me -- as well as the treatment documents, are related to whether or not there was a violation of the antikickback statute. And it's relevant to whether the claim that the information given was clinical pretext or whether it was clinically supported, and it's relevant to whether or not the conduct was genuine patient education and counselling, or was it inappropriate, quote unquote, sales-oriented activities and

promotion.

And so these documents are relevant to establishing that Novartis's defense, which is its conduct here was entirely appropriate.

Now, the government also raises several other non-relevance type objections, which I can cover now or in rebuttal if your Honor would prefer.

THE COURT: Go right ahead.

MS. SHETH: Okay. Thank you, your Honor.

The first argument is that this is a fishing expedition by Novartis, and I would strongly disagree with that. Because we have in our discovery request identified the specific programs that we were able to find just from a public search using the internet. And we've identified the specific agency within the government who we believe would have relevant documents. And one of the important points to note -- it's actually in response to their burden argument -- is that we're not asking -- and this primarily applies to the states -- that we're not asking that they search every single state entity within the rubric or umbrella of the state government. But it is limited to agencies that have some responsibility over healthcare policy, particularly adherence policy, and adherence initiatives.

Second, it's a very limited subset of documents that pertains to adherence initiatives, the Government's views on

adherence initiatives, and issues relating to whether something is -- whether marketing is, excuse me, whether adherence initiative are excluded from marketing activities.

And then the second argument they make -- the federal government actually makes this argument more so than the states -- is that because the government views its adherence programs as substantially different than what Novartis was doing in this case or alleged to have been doing in this case, the discovery is not relevant. And I think that argument, sort of that self proclaimed proposition doesn't really work here. Because if that's the position of the federal government, we need those documents to test that assertion, that these adherence programs sponsored by the government are vastly different than the adherence program that's at issue in this case. So I don't think it's appropriate for them to simply say that we're not going to produce documents because the two programs are vastly different.

And then again, as your Honor noted, the burden argument is also heavily relied on both by the federal government and the states. And here there has been, to date, no factual support that the government has provided in support of their burden objections. And the case law in this Court is clear that a party, including the government, cannot rely on generalized claims of burden to avoid producing documents. They have to come forward with specific facts that support its

burden objections. And here, given the very narrow categories of documents that we are seeking on both categories, we think there is not merit to -- there is no merit to the Government's argument on burden. And we're also limiting it to certain specific agencies within the government that have responsibility over these two categories of documents.

And the other point I would make with regard to the burden argument is that we received very little discovery to date from the states particularly. All the -- three of the 11 states who are plaintiffs in this action have produced only claims data. So we've not received any other documents from all the three of the states.

And with regard to the remaining three states, New York, for example, has produced a mere 117 pages of documents in addition to their claims data. Wisconsin has produced 570 pages of documents. And so we're not, you know, we're not in a situation where the government has produced so many documents and we continue to ask them to produce more documents and more documents for no reason. These are clearly relevant documents that go to the heart of the issue, whether or not there has been an antikickback violation in this case.

Now the last argument that the states make is that they are not in custody or control -- possession, custody and control of the documents. And their first argument on that point is that it is the SSA, the single state agencies, not the

states who are the plaintiff in this case. And we would disagree with that. Because the real party, if we look at the complaint, the party who's named in the caption is the state. The state is arguing, well, no, it's actually the SSAs because the SSAs is the party who incurred the damages and that's who will get any recovery, to the extent there is a recovery.

But again that misses two points. The first is that is the test of production of documents has always been -- the real party in interest is not the party who suffered the damages, but rather who is the party who brought the case, who is the party that has possession custody and control of the documents. So that argument by the State is not supported by the case law.

And if we actually look at the Government's state complaints, each of them alleges that in the damages section that it is the state who has suffered damages here, not the SSAs. But even accepting for a moment that the SSAs are the true party in interest, we have to look at the regulations and the statutes which show that the SSAs each do have the practical ability to get these documents. The SSAs have control over the documents of state agencies, as well as state run hospitals who are involved in the administration of Medicaid -- of the Medicaid program or that provide Medicaid services. And although the states argue that this should be limited to -- the states are limited in their authority to

entities over whom they conduct audits, that's not what the regulations say. Actually the states have authority over anyone, any Medicaid provider who is involved in the administration of the Medicaid program. And to be clear, we are not asking states to go out to every individual healthcare provider who is a Medicaid provider; but, rather, we're talking about the state entities who are charged with administering the Medicaid program. So it's not as burdensome as they would like to make it out.

THE COURT: Well, but your legal argument would logically lead to that result, would it not? Your position is that the regulations dictate possession, custody and control, and that gives them audit capabilities over the individual providers.

MS. SHETH: According to -- I mean, that's probably literally how the regulation reads. But I think what we are seeking here, those documents -- well, first of all, the adherence documents generally won't be at the individual healthcare providers because those are going to be more policy adherence initiative type documents. Those are going to be at the state entity level.

And then as to the treatment protocol documents, we're not looking for individual patient records on why particular patients -- what was in the thought process of healthcare providers for individual patients, but rather more generally

what is the guidance that's given at these government run hospitals.

THE COURT: Thank you.

MS. SHETH: Thank you, your Honor.

MR. YU: Good morning, your Honor. Li Yu for the government.

THE COURT: Good morning.

MR. YU: Let me start by going to an issue of where we are in this case today because Novartis just has just -- it's plain in its view what has been decided and what has not been decided by the district court on the motion to dismiss. And I think I do want to start by kind of going back to that point. You know, in the decision, in her decisions Judge McMahon did decide a question of what constitutes antikickback violations in this case, and that's very important. Because ultimately that is a question that Novartis purports to seek discovery in this instance and that, you know, any relevance or non-relevance documents has to be evaluated based on the legal standard of what is an antikickback statute violation and what is not.

So what the antikickback statute itself prohibits a party like Novartis for giving remuneration to another person, including pharmacies in order to induce the pharmacies to recommend their products. And so each of those terms which Novartis -- you know, Ms. Sheth had mentioned recommendation,

inducement, remuneration, all of those are defined within the statute itself. And so ultimately those, what those words mean and how, what they mean in the context of this case is now being driven ultimately by what some government official may see, may think in the context of some program, ultimately those are words that have commonly and well accepted meaning. And in the context of construing them, the Court will construe them based on, based on what the words mean and based on precedents dealing with those terms.

And so as a starting point Novartis, what Novartis is arguing which is, you know, somehow the government, how the government views a given adherence program is somehow binding or relevant to the question of whether or not there has been a kickback statute violation. So that point we disagree with. So now --

THE COURT: Let me stop you there for a second. Is the upshot of that argument that you could bring an action based on the False Claims Act against Novartis based on adherence program that is identical to the one that the government operates?

MR. YU: Well, your Honor, I mean there are a couple basic points. One which is -- I mean the government cannot -- I mean, as much as Novartis claims or argues there are strong similarities between what Novartis is doing and what the government does, I mean there are realy no similarities.

Because the government, unlike Novartis, is not a drug maker. So while Novartis here is the party that makes the drugs and distributes the drugs and the government is either a payor in the case of Medicare, or it has no service provider in some cases. So there are some very fundamental differences in terms of how parties are situated.

And moving even beyond that, I mean the government itself is very differently situated from Novartis. The government as a sovereign is not, itself, subject to the antikickback statute anyway, nor does the antikickback statute have any exception as, you know, if there is a similar government conduct, then Novartis a, private party could somehow find its conduct exempted simply because its conduct is similar to the Government's conduct. I mean, and here especially where Novartis could have -- where Novartis -- if they had argued or if they had made its point maybe some way relevant would be, if they had based or modeled or relied on some part of government conduct or something the government did in terms of what it's doing here, you know, I mean we don't think that's relevant, but at least I think that would be, you know, there would be some argument about its knowledge of what the government is doing or how the Government's operating its programs that may be relevant to their intent, Novartis's intent at the time it did what it did. But here Novartis actually as it said on page ten of their opening brief, that it

has not modeled its conduct on any government programs. And so the idea that, that the government may offer some program, operates some program that Novartis that may be certain respects or Novartis may argue that it's similar to what it is doing, or what it was doing, that ultimately, while that could have -- they could have argued that that was relevant to their intent or their knowledge, in fact, you know, that issue is not -- that question is not at issue here.

THE COURT: I think you just answered my question yes, which is that the government does take the position that it can go after Novartis for conduct that is identical to that which the government is engaged in because the government is not subject to the antikickback statute.

MR. YU: Yes, your Honor.

THE COURT: Okay.

MR. YU: I mean, not only is the government itself not subject to any kickback statute, also the statute doesn't have any exception or any safe harbor saying that exempts private parties from liability for similar government conduct or some type of protection like that. I mean, so here neither of them applies here.

THE COURT: Let's assume that to be the case. So the information that Novartis is requesting would not be relevant for the antikickback claim, why would it not be relevant for the other claims, the common law claims at least in the state

complaints, unjust enrichment, for example?

MR. YU: Well, I mean, your Honor, for both -- well, both the unjust enrichment and the False Claims Act claim are based on the same underlying violation. The Government's argument is basically that -- the government claims really has two parts or the government claims would have two parts to it. There is, basically, the underlying issue is Novartis violated the antikickback statute. That gave rise to falsity, and that falsity resulted in false claims. Some of the government has claims under the False Claims Act which provides statutory damages and penalties, but also has common law claims. So in this case -- I mean so what Novartis is asking, why it wants discovery is to attack the underlying claim or whether or not engaged in underlying violation. And so the same standard of relevance governs whether or not the underlying violation occurred or didn't occur, whether or not, you know, the government is seeking remedies under the False Claims Act by statute or by common law through unjust enrichment or, you know, unjust enrichment as to Novartis.

THE COURT: Are you suggesting that the Government's unjust enrichment claim is co-extensive with the antikickback claim -- False Claims Act claim?

MR. YU: Well, your Honor, I mean they have the same underlying premise which is, you know, the government has been injured whether it's, you know, by way of statutory injury or

in this case by way of a common law injury. Because there has been -- the government has been -- paid out money or has given people money based on a false representation or false certification. The false certification in this case is what is -- these claims are part of a relationship that complies with the antikickback statute. And so the Government's claims, whether it's under common law or under the False Claims Act, all arise from the underlying antikickback statute violation.

THE COURT: I guess my question is because unjust enrichment involves a balancing of the equities, which is not something necessarily we have to do under the False Claims Act, wouldn't the Government's conduct become relevant in conducting that balance?

MR. YU: Well, I mean I think, your Honor, in this case, it's not an issue that has been squarely raised, and so we can certainly, you know, look further into that. But, you know, standing here I think the answer is the Government's -- I mean, the Government's conduct doesn't -- because -- I mean, the government has been -- Novartis has been unjustly enriched if, you know, there is a conclusion that it has been unjustly enriched because its conduct violated the antikickback statute and caused false claims to be paid out. And because the government and Novartis are fundamentally differently situated under the antikickback statute. So because the government itself is not subject to this statute, so how the government,

you know, so how the government structures its affairs and conducts its programs doesn't really go to the question of any private parties compliance or noncompliance with the antikickback statute. So I don't think that the fact the government, even if it were true -- which it wouldn't be true because the government is so fundamentally different situated from a drug maker like Novartis, even if it were true that these programs are -- have great similarities or even identical, that still wouldn't really affect I don't think through the equities balance analyses as part of the unjust enrichment claim.

THE COURT: Let's go back to a second to the False Claims Act claims. I asked Ms. Sheth a question about the scope of the Government's claim there, and she suggested to me that it's much broader than I had opined. Perhaps you can outline for me exactly what the Government's claim is and how broadly it ranges.

MR. YU: Yes, your Honor. So I mean the government, part of this is based on two decisions that Judge McMahon issued as part of the response to Novartis's two motions to dismiss. So the government -- there are basically, again, there are two aspects or two parts to the Government's False Claims Act claim. There is the underlying violation which is the, which is a series of relationships between Novartis and pharmacies. Novartis and pharmacies violated antikickback

statute, Novartis, they violated the antikickback statute because Novartis offered and give remuneration in this case, patient referrals and rebates in the Exjade scheme and the rebates in the Myfortic scheme to the pharmacies. And the pharmacies agreed in return for those types of remuneration to make recommendations in favor of Novartis's drugs. And here, your Honor, I just want to make one point, which is --

THE COURT: Let me stop you there, because I think I'm at a point where I need additional information. Is it part of your claim that the decision the pharmacies were making and the advice that they were giving to patients in terms of adherence programs or whatever, were not clinically indicated?

MR. YU: No, your Honor, that is not an aspect of the government -- that's not an element of the Government's claim here. This is fundamentally not a case -- it's not a medical malpractice case and it's not a case where we are arguing that -- this kind of goes into the second part of False Claims Act case which is we're not arguing that the claims in this case are false because they're not clinically indicated or the drugs were not medically necessary. So there are cases like those, but this case is not -- this is not that type of case.

Here the claims were false, and Judge McMahon decided this, you know, every single claim within the context of the relationship that was a kickback relationship was false, because the relationship itself was what violated the

antikickback statute and that, in turn, led to certain certifications, and so that gave rise to falsity. But in this case the Government's claims A, are not limited to instances where the drugs were medically not necessary or not clinically indicated and, two, that's not an essential element of the Government's claim. I mean, you know, let me if your Honor if I may just kind of walk -- Novartis in its argument does raise this issue and say, well, the government's complaint talks about the questions of clinical independence versus, or the government complaints talk about recommendations being made in a way that's not independent, that doesn't reflect independent clinical judgment. And there what we're talking about is not whether or not in some objective way, you know, whether an expert would say oh, well, that recommendation is medically appropriate that recommendation is not medically appropriate, but it really the question is was the recommendation, whether it's right or wrong, induced; was it something that was in part motivated by the financial considerations that Novartis injected into its relationship with the pharmacies.

Your Honor, one example would be paragraphs 151 to 160 in the Government's most recent complaint where it talks about a relationship Novartis had with a pharmacy called Bryant's. So the relationship started with Novartis offering Bryant's rebates, and we allege in exchange Bryant's agreed to recommend Myfortic and to move patients from a competitive drug to

Myfortic. So this happened for a period of time. And then generic competitor to Myfortic came to market. So initially as the rebates continued to flow from the Novartis to Bryant's, the owner of Bryant's was happy to keep his patients on Myfortic. He argued that it was important that patients -- in fact one of the arguments counsel made here, it was important for patients to keep staying on Myfortic because there is no clinically -- there is a benefit of continuing the same therapy. Lo and behold, you know, as the situation -- as more patients started using generic rather than the brand name drugs, the amount of rebates going from Novartis to Bryant under their preexisting arrangement began to ebb so there was basically went from torrent to a dribble, and at that point the owner of Bryant told Novartis look, you know, this isn't working, I'm going to go ahead and recommend other patients switch over from Myfortic to the generic. And Novartis's response to that -- we really want you to keep these patients on Myfortic, so we'll actually rework the terms of our arrangement and retroactively rework their arrangement. And going forward again the owner of Bryant kept arguing that patients should stay on Myfortic rather than switching to generic or using a competitor drug.

And so in this case, so that kind of illustrates a basic point, which is what is problematic, what is the violation of the antikickback statute is not because the

government believes generic is better than Myfortic, or because Myfortic is better than generic. No, that's not really our issue. The issue we are concerned with is the way that financial considerations drove or at least factored into the decision that the pharmacy made. The pharmacies -- whether Myfortic is better or whether generic is better, I mean, there can be debate about that. But what is clear, one cannot be better than the other if the pharmacist happened to be getting more money from Novartis, and then the pharmacy is getting less money, then the other one became a better drug. So fundamentally it's not a of based on objective standard, you know, which recommendation was more appropriate. It's rather the question of whether or not the financial considerations Novartis brought into the relationship, put into the relationship factored into the pharmacist's judgment. And that ultimately doesn't really depend on the question of whether or not a given recommendation is facially valid in some way. Novartis may very well decide to offer testimony or offer evidence through an expert that this is relevant. We disagree. But fundamentally we don't think it's relevant because what matters for the antikickback statute is whether or not the recommendation, which has a commonly accepted well understood meaning, and in fact Judge McMahon has already opined on this page 34 of her May decision, whether their recommendation was induced, whether it was motivated in some way by the financial

relationship between Novartis and the pharmacy.

Your Honor, and the same argument applies to -- again applies to the Government's allegations about the Exjade relationship. You know, there the government, as counsel pointed out, the Government's complaint describes how Novartis's relationship with BioScrip or how the types of benefits that Novartis offered to BioScrip created a situation where BioScrip structured its refill program such that the program was focused not on patient care, but instead on the question getting more refill orders. And, again, there Novartis makes the argument, well, we don't know what the recommendation is. I mean, we let you know on this point there is a pretty clear definition of recommendation. Miriam Webster, for example, says a recommendation is to saying something -- saying that something is good and deserve to be chosen. And in this, in the context of Exjade what was happening from Novartis's perspective, what led to the scheme was Novartis knew that a number of many patients were, for variety of reasons not ordering refills. So there was a decision that patient had to make, were they going to order a refill or not going to order refill. And when Novartis through its relationship with BioScrip, you know, motivated BioScrip to do with these incentives is for BioScrip to have its people tell, advise patients that they should order, they should order refills. So that, you know, very clearly is a recommendation.

Novartis doesn't need to go to the Government's files or go elsewhere to decide or to understand whether or not telling or advising someone who maybe was reluctant to order something that it should do it, they should go ahead and choose to order a refill whether that constitute a recommendation.

THE COURT: And it's your position that it's not pertinent whether or not it was a good idea to make that recommendation?

MR. YU: Your Honor, right. Again, whether or not, by some objective measure that recommendation was clinically appropriate or medically appropriate is -- that is ultimately not relevant. You know, what is relevant is what Novartis and the pharmacy, in this case BioScrip, they understood -- what they understood their relationship to be and what Novartis understood BioScrip to be offering to Novartis, would be doing for Novartis in return for these benefits. I mean, the government, just to be clear, the government does have allegations that talk -- that describe and that go to the nature of how BioScrip operated its program. But that's really -- I mean, those allegations really ultimately go to the question of motive and intent and Novartis's argument about wilfulness. Because the allegations show is on one hand Novartis and BioScrip were telling the world, were telling their patients, telling prescribers that what they were doing was a patient center program, patient focus program. And what

in fact they were doing was as the evidence will show is they were focused on getting as many orders, shipments out the door as possible so that Novartis in its own word, its own words could meet its national sales target. So, again, so the question is not whether or not a particular piece of advice was medically right or medically wrong, but instead the question is was Novartis motivating BioScrip to do something that was consistent with BioScrip's responsibility towards patient care or was Novartis basically, basically subverting that, subverting the pharmacy's responsibility and make pharmacy focus on, you know, focusing on the target and Novartis set for the pharmacy in terms of numbers of orders and numbers of shipments.

THE COURT: Well, why is that important? Even if BioScrip was going to act in precisely the same manner that it did before or after it received remuneration, isn't it your position that it would still be an antikickback violation?

MR. YU: Your Honor, I mean I think certainly, the Court, Judge McMahon did in fact -- sorry -- did decide that even if there are no steps taken in furtherance of an illegal agreement, that could still be a violation. So, you know, on one level all that needs to happen is there has to be a legal agreement. But in this case our allegation, as you say, do indicate that BioScrip did in fact take steps and did make recommendations. This was not simply an inchoate scheme. The

scheme did progress over a number of years, and during that time BioScrip did make recommendations being motivated by the financial considerations.

THE COURT: I guess my question really goes to causation; that is, that those the steps that it took, do you have to prove that the steps that it took were different than the steps that would have taken had it not been remunerated; that is, that it would have given different advice?

MR. YU: Your Honor, we don't have to -- that's not an element we have to prove because Judge McMahon in fact decided this question of whether or not a scheme has to succeed in order for there to be antikickback violation. She said very clearly that it's the illegal arrangement or it's the kickback arrangement itself that constitutes the antikickback statute violation, and not a success of the scheme. So, in fact, the government doesn't have a burden in this case to prove that the scheme succeeded.

Your Honor, let me sort go back, just go back and address the adherence point, and I'll touch on some of the burden points that were discussed earlier as well.

So on the adherence point, it's logically -- we've already -- I've already discussed some of these with the Court. The adherence point, Novartis posits that it needs to have Government's view about what constitutes a recommendation, what constitutes proper versus improper incentives, and what

constitutes adequate or inadequate training. You know, first of all, what constitutes recommendation? As I mentioned earlier, I mean, that's ultimately a legal question. The word recommending appears in the statute itself, and we believe Judge McMahon has already opined on the question in the context of the two schemes, what constitute or doesn't constitute -- what constitutes and doesn't constitute recommendation. So for Novartis to now try to go through the Government's files and try to dig up the Government's view, we don't just don't believe it's ultimately relevant.

Secondly, as far as proper and improper incentives, again, in terms, you know, the statute itself defines what remuneration is and defines what inducement or relevant between remuneration and recommendation through abuse. So those are all legal questions, you know, that are going to be answered by the Court. Whether the government views them one way or another in the context of some unrelated program is really not relevant here.

And finally the question of metrics. Again, the government is not suing Novartis because, you know, we assert that by some objective measure Novartis used the wrong metric. I mean this ultimately, this is not case about malpractice about Novartis did something that was inconsistent with some type of standard of care. I mean, this is case is fundamentally about the way in which Novartis structured its

relationship. And I mean Novartis says it needs documents from the government to know whether or not the way it operated the Exjade scheme was sales oriented or not. I mean, I really think that's really kind of a red herring. I mean here we have Novartis document very clearly say that -- this is discussed in the complaint, I believe page, paragraphs 279 to 296 where Novartis documents very clearly say they were basing the incentives, they were offering BioScrip on whether BioScrip helped Novartis fulfill their national sales target. I mean, the idea that somehow Novartis having said that in its own documents somehow needs to go to the Government's files and look through those files to understand whether or not what happened here were sales oriented or not sales oriented, I mean we really don't think that carries water. And ultimately it's just irrelevant to the question of whether the relationship constituted the kind of inducement relationship that's prohibited under the antikickback statute.

And, finally, on the question, your Honor, of burden. I mean, here -- I mean, because of all the information that's publicly available and so -- I mean, because the government operates in the public, it's not a private company, that's somehow hiding this information so, you know, perhaps we could have done more or could have done more in terms of explaining the burden. But just give one statistics -- I mean Novartis, among other things, asks in one of its requests for adherence

programs or other similar type of initiatives across all of the VA healthcare facilities. There are 151 medical centers that are operated by the VA across the country, and on top of that you have some I think approximately 830 outpatient clinics. So the total volume or the total sources of information that Novartis is seeking here is very very broad and it's very very, very very sweeping. And so certainly that type of discovery request, Novartis hasn't justified by way of any type of prejudice. I mean Novartis -- earlier Ms. Sheth has noted before the general principles about scope of discovery. But ultimately there are some serious -- we don't think any of this request is -- any of the requests Novartis has made are ultimately relevant. And certainly in this context Novartis hasn't cited to any case or any authority from a False Claims Act case or from a kickback case where a court has permitted this type of sweeping discovery into all types of government programs, government initiatives, government -- and government protocols. We think there is a good reason for that, which is I mean because in a case like this the government, by virtue of being a fundamentally differently situated from the private defendant, those type of discoveries is ultimately irrelevant. And by virtue of the size of the government and programs it operates are highly burdensome. And so it's not surprising that there is no authority that Novartis can point to. And for Novartis to ask the Court here to require the government to

respond to these irrelevant discovery requests, we think is really -- it's, again, itself unprecedented and really cuts against the concept of relevance and also cuts against the basic elements of the claims of defenses that are at issue here.

THE COURT: Thank you.

MR. YU: Thank you.

THE COURT: Who shall I hear from from the states first?

MR. MILLER: Good morning, your Honor, Chris Miller from the Office of the Attorney General of the state of New York.

I won't repeat everything that Mr. Yu said. I want to start, however, with the concept of discovery needing to be relevant to claims and defenses in an action.

In this case, as Ms. Sheth said, it needs to be relevant to one of those two things.

And with respect to the antikickback statute, I don't think the discovery that's sought here which, for instance, in the case of Novartis requests asks for the views of state government officials about adherence programs is relevant. The laws and statutes, laws and regulations and other official pronouncements is not in the musings of state government officials in their power points or in their e-mails. In one of the exhibits attached to Novartis's papers, for instance, there

is a power point in which there is a discussion of providing incentives to prescribers in order to use e-prescribing as opposed to faxing prescriptions, and how that would reduce mistakes. And there is an off handed comment about how that may also promote adherence. That is not a statement on the law. That is not something that Novartis needs to take discovery of to understand what its obligations are in this case. That is forcing us to go through our files to find every reference to adherence and produce it to Novartis. And it doesn't matter what someone says in the power point slide internally, and it certainly has no bearing on Novartis's state of mind, which is the other principal argument that I think they raised in their initial papers.

I agree with a lot of what Mr. Yu said so I won't go through everything else. I will say that, you know, we certainly did agree to produce some documents in the spirit of compromise concerning Exjade and adherence programs from our single state agency. We did not make the concession that Novartis stated that we made it earlier today. And I think that, you know, we've heard today some things that we frankly hadn't heard before. There are a list of state agencies in the discovery request from which they wanted discovery, but the request themselves, the wording of them was not in any way so limited. So we would have to go to every agency. It's nice there's some willingness to focus on policy making functions.

But I would say that I think we've gotten there already from the state perspective; in other words, our interest in this case concerns the state Medicaid programs, and we are producing documents from the policy maker for the state Medicaid programs concerning Exjade and adherence programs. So, you know, I think we've come up with a reasonable compromise and the Court should accept that compromise.

And I think I'll turn it over now to my colleague Steve Ross from California, who will talk a little bit about possession, custody and control.

THE COURT: Thanks.

Mr. Ross.

MR. ROSS: Thank you, your Honor. Your Honor, the only thing that I want to repeat that Mr. Miller said is that there was no concession, as Ms. Sheth said earlier, about the relevancy of any of Novartis's document requests. What we did we did in the spirit of compromise in the hope that we wouldn't find ourselves here.

But what we did was we limited our search to the issues relevant to the case, Exjade and the Medicaid system because as Mr. Miller said this case is about, from the states' point of view, the Medicaid system and the damage or the injury that the states' Medicaid systems sustained as a result of the kickback scheme.

One of the points that Novartis is trying to make here

is that we as -- and I'm not sure what she's -- what she means, but we as either the Attorney Generals of the various states or the single state agencies, or the states themselves, are able to somehow reach into, excuse me, reach into the files of sister agencies in the state and produce documents, or obtain documents or control documents. We don't have the ability to do that, and the law says that we don't have to do that. In fact, I think the leading case which is a New York case, the Boardman case, which I know we dealt with in the state's objections to the pending motion, said that -- the Court said very specifically, there is a presumption that separate governmental agencies under state law will not be aggregated together without the showing of much more. It doesn't matter whether the particular plaintiff in a particular case is an agency like the Department of Transportation in the Boardman case, or the state itself as in the Lokear case in California which stands for the same proposition. In fact, the Boardman case went on to say at page 266, that if you followed the defendant's argument, in other words, that the state can reach into any sister agency to produce documents -- if you follow that argument to a logical conclusion, any lawsuit brought by the State of New York would subject all 22 executive agencies, et cetera, et cetera, to discovery. The Court could easily have said any lawsuit brought by a particular agency would open up any other agency, any other agency's files. The Court

didn't say that. It said the State of New York. So it doesn't matter, for purposes of this issue, discovery issue, whether it's the state that's the party in interest or whether it's the single state agency that's the party in interest. And we've conveyed that to Novartis; that for purposes of this issue, because of the loss, particularly in Boardman it just doesn't matter. Boardman says there's a presumption that you don't aggregate a sister state agencies without much more. The much more is the burden that Novartis has in this case. If they want us, as either the Attorneys General or the single state agency to go into a sister state agency and look for documents, they have to meet their burden to show this Court that we, in fact, have the ability to do that.

THE COURT: Well, Ms. Sheth says she's met that burden by pointing you to the regulations that provide you with the ability to audit.

MR. ROSS: I understand that. And those regulations are very limited in scope. Those regulations relate to the Medicaid, program. They allows us to go into and audit, but it relates to the Medicaid program. The requests that Novartis is asking the states for are not limited in any way to the Medicaid program. We don't have the ability to oversee or investigate any sister state agency for any conduct other than perhaps conduct directly related to the Medicaid program. That's not what they asked for.

You know, we tried to compromise with them on those issues, but they refuse. Their requests are so broad and go so far beyond just the Medicaid system, that it's not possible to respond in an intelligent and reasonable way, the way the requests on this motion are drafted.

THE COURT: I'm not sure I understand the significance of saying that the authority is limited to the Medicaid system. If the claim here is based on the fact that the Medicaid system is being defrauded by Novartis, why isn't the information that she's seeking related to the Medicaid system?

MR. ROSS: Well, first of all, if Medicaid wasn't paying for it, for example, if it wasn't something that had to do with Medicaid population, it wouldn't have anything to do with this particular action. The program may have nothing -- the programs of these sister agencies may have absolutely nothing to do with anything that goes on in the Medicaid system. It may be a program that the Medicaid system doesn't have. I don't know at this point. You know, we don't control those other agencies or the documents they have. I think the burden is on -- the point I'm trying to make is the burden is on Novartis to show that we would have some custody or control over particular types of documents, in particular sister agencies, and they haven't met that burden.

THE COURT: Thank you.

MR. ROSS: Thank you.

THE COURT: Let me see if anyone who has joined us telephonically would like to weigh in. And what I will do is go down my list and ask you if you would like to add anything.

For the State of Georgia, Ms. White?

MS. WHITE: No. Thank you, your Honor.

THE COURT: Illinois, Ms. Hamilton?

MS. HAMILTON: No. Thank you, your Honor.

THE COURT: Indiana, Mr. Carcare.

MR. CARCARE: Your Honor, the only thing I would like to add to the argument is that Ms. Sheth had argued that there was a very limited group of entities. With respect to the Indiana, one of the entities that Ms. Sheth's client has been asking documents for is the Indiana University Hospital, which is a private corporation. So your Honor's argument that the logical extension of Ms. Sheth's argument is that the discovery would be seeking information from actual providers other than the state, is borne out by the very fact that they've asked for information from the Indiana University Medical System.

THE COURT: Thank you.

Mr. Dykes, from the State of Maryland?

MR. DYKES: No, your Honor, I don't have anything additional to add. Thank you.

THE COURT: Thank you.

Mr. Robinson for Oklahoma?

MR. ROBINSON: Your Honor, like Indiana, the hospital

Novartis is seeking discovery from are private corporations.

THE COURT: Thank you.

Ms. Wilson from Wisconsin?

MS. WILSON: I have nothing to add, your Honor. Thank you?

THE COURT: And Ms. Bashaw for State of Washington?

MS. BASHAW: Washington's fine, your Honor. Thank you.

THE COURT: Thank you.

Ms. Sheth, you have some rebuttal?

MS. SHETH: Thank you, your Honor. I will be brief.

Let me begin just with the point about Judge McMahon's decision. That decision, as your Honor knows, was based on the pleadings. The judge did not rule that Novartis violated the antikickback statute, but rather merely ruled that based on what the government has alleged in the complaints, accepting those allegations as true, they had sufficiently pled a cause of action under the FCA based on the predicate AKS violation.

THE COURT: But isn't one of the significant things about her decision the extent to which she limits the complaint; that is, her interpretation the antikickback allegations may well serve to limit the discovery by rendering at least some of what the government has included as fluff?

MS. SHETH: Well, it is interesting that, you know, the government, what we heard today from the government is very

interesting. Because -- well, one, if we look at the allegations in their complaint they're not consistent with what we heard today.

But I think what is very significant is that after Judge McMahon's decision came out, the government issued several subpoenas to the specialty pharmacies. And one of the categories of documents that the government requested in those subpoenas was communications between the specialty pharmacy and physicians relating to CellCept, Myfortic and switches of patients from CellCept to Myfortic.

And, in addition to that, they also requested documents that show the identity of the specialty pharmacy personnel and the physicians involved.

So given that, they're still serving discovery requests that go to this issue about whether the -- what were the communications, are the communications pretext or not. And I think with regard to Judge McMahon's decision, she was really ruling on the issue of causation. So Novartis in its briefing on the motion to dismiss had argued that the government must show some causal link between the inducement provided to the SP, the specialty pharmacy, and that pharmacy's then influence on the physician, and did that physician write the prescription based on what they heard from the specialty pharmacy or for other independent clinical reasons. And we said -- we had argued that that should be -- they have to show that there's

some causal link in that chain which ultimately led to the submission of a false claim. The Judge rejected that argument which really went to this causation issue. I don't think that she ruled on what is the proper parameter of an antikickback statute violation, specifically with regard to what constitutes remuneration, what constitutes recommendation and what constitutes promotion of the Novartis products.

THE COURT: Well, let's go back to Mr. Yu's point on that. How does any of the discovery that you've requested illuminate what sounds like statutory terms?

MS. SHETH: Right. And so Mr. Yu definitely makes that argument. And I think the words in the statute have to be informed by the facts. And if we look at the actual policy rationale of the antikickback statute, it's based on avoiding over utilization of products and services. It's intended to avoid patient harm, and it's intended to avoid improper influence or corruption of healthcare providers clinical judgment. And if you look at the Government's complaint, those allegations in the complaint bring these issues squarely into play. And I will just read several sentences from the Government's complaint that reflect this. If we look at paragraph 227 of the second amended complaint of the U.S. Attorney's Office, the first sentence of paragraph 227; "Further as Novartis and BioScrip were aware, the calls from BioScrip did not provide Exjade patients with unbiased clinical

information. Instead, and unbeknownst to the patients, those calls emphasized the benefits of getting refills and down played the significance of Exjade's side effects."

And even Mr. Yu's presentation today when he was talking about Bryant's, talked about the actual conversation between Bryant's and Novartis and the SP -- excuse me -- between Bryant's and the physician relating to clinical benefits of Myfortic, and are these appropriate clinical, clinically supported benefits or are they simply pretext.

With regard to Exjade, if we look at paragraph 274 of the Government's complaint, they allege these recommendations to patients to order refills or to restart Exjade therapy, however, were not based on independent clinical assessments of whether a refill or restarting Exjade therapy was needed or clinically appropriate.

They also in their complaint challenge how Novartis measured adherence. Novartis used refill rates. At paragraph 286, the government contends that the refill is not an appropriate measure of adherence and, rather, they should be looking at how many patients were actually adhering to the medication as prescribed by the physicians.

And even if we look at the Government's own statements of its representatives at various hearings. For example, at the March 14th hearing in front of Judge McMahon, the government stated, "Because of the way the recommendations were

made, they were made under the pretext of certain clinical justifications, and the result was, in many cases, that patients were switched from a competing drug to Myfortic."

With regard to Exjade, there was another statement that the Exjade scheme was really a matter of corrupting the medical judgment of the pharmacy. BioScrip was just pushing the drug on patients without knowing the precise medical conditions that the patients had.

You know, so these statements and allegations in their complaint really put these issues squarely in dispute, and we need to be able to have the discovery that allows us to show that what we were doing was not corrupting the physician judgment. We were providing truthful, accurate, clinically supported information. We were not engaged in inappropriate sales oriented activities or promotions or recommendations, but rather completely valid and appropriate education and counselling activities.

Now, what the government -- their views on what an appropriate adherence program is, would shed light on these various legal elements which go to inform the plain language used in the statute.

Now, the government also argues that Novartis has to be aware of and has to rely on these specific adherence documents in order to make them relevant. But what they miss is that we have two statutes at issue here. We have the False

Claims Act, which has a knowing intent element, and we also have the antikickback statute which has both a knowing and a willfulness intent element.

And the wilfulness is key here. Because part of the definition of wilfulness is, under the AKS is whether the conduct is so obviously evil, so inevitably nefarious, so inherently bad that no one -- that everybody would have known that this conduct is prohibited. And the government cites to three cases in their papers, the Prabhu case, the BankAtlantic case and the Elsass case. None of those cases involve the question about wilfulness under the antikickback statute. And in fact Prabhu involves the knowingness, knowingly standard under the FCA, whereas Bankatlantic and Elsass involve two completely different statutes. And so this discovery is relevant to whether or not Novartis's interpretation, that Novartis's understanding that its activities were lawful, they were not prohibited under the antikickback statute is a reasonable understanding, that its conduct was appropriate under the statute.

Now, I mean, given that we were surprised to hear sort of how sterile the government expects its case to be, I mean if the government is willing to concede to strike some of those allegations that I reference in its complaint, then that certainly will change what is relevant in this case. And if they're going to proceed strictly on a disclosure theory, I

think that would be good to know.

You know, just what we've heard so far is here's what they have put in their complaint, here's what they've argued at the various hearings. And even today we're hearing that it is still -- they're still putting into issue these communications between the specialty pharmacy and the various healthcare providers.

THE COURT: Well, there is a difference, is there not, between that which they will have to prove in order to make their case and that which they want to expose to the public?

MS. SHETH: That may be true. But if they're going to put these -- if they're going to put on proof of these allegations as part of the effort to describe the overall scheme that they're alleging with regard to Myfortic on the one hand and Exjade on the other, and if they're going to put in evidence at trial that goes to describe this overall scheme, how the scheme operated, how Novartis corrupted the clinical judgment of both specialty pharmacies and healthcare providers, then we need to be able to respond and say, no, actually what we were doing was just simply providing truthful, accurate information, and look at what the government itself views as truthful, accurate information. So that, you know, it is certainly relevant to establishing one of our defenses.

Turning just quickly to the state's arguments. Again, the state actually relies pretty heavily on the Boardman case.

But that case, one, is from the Northern District of New York. But more importantly it can be distinguished on three very significant bases. First, in that case the Court found that the true plaintiff was actually the Department of Transportation and that the State of New York was just a nominal party. That's very distinguishable than what we have here. Here the caption is brought by the -- mentions the various states. The allegations in the complaint mention that the states are the damaged party. And so here we have the plaintiff as the state, not a specific agency within the state.

Second, the Court's decision in Boardman was focused -- relied very specifically on provisions within the New York Constitution, which found that both the comptroller and the Office of the State comptroller was totally autonomous from the Governor and the rest of the executive. So there's very specific constitutional language that the court relied on to hold that those two entities, the Department of Transportation on the one hand, and the Office of the State Comptroller were two different entities, and that the Department of Transportation did not have access or the practical ability to obtain documents from the Office of the State Comptroller.

And, third, which is really the critical point, is that in that case the Court distinguished the case that Novartis cited, which is the De Campagne Francois Phillips

Petroleum Case, which is from the Southern District, but recognized that the key issue was whether or not the state -- would have to -- the key issue in deciding whether or not the state would have to produce documents was whether the state had possession, custody and control of those documents, and the Boardman case recognized that the concept of control is a broad concept, and if a party has the practical access and control over the requested documents that they should be produced. And that's what we have in this case, where we are showing by virtue of the regulations that the SSA do have the practical ability to get access to those entities, those state entities that administer the Medicaid program. And even a case that was decided both after Boardman and obviously after the Phillips Petroleum case, this is the Gear v. Skelly case also notes that Boardman, the Boardman distinguishing concept of control is still applicable today. And in that case the Court ordered that documents should be produced from a non-party -- in that case it was the Department of Corrections -- because the Department of Corrections was sufficiently closely coordinated to the party at issue, such that it had the practical ability to obtain those documents.

So I think the Boardman case can be distinguished on a number of grounds, but it still stands for the fundamental principle that the state has the practical ability to get documents from the state, the single state SSAs, and those SSAs

have the ability to get documents from those entities who are involved in the administration of the Medicaid program.

And then finally as to the state's burden argument. From the presentation, it sounded like there was some ambiguity about whether certain agencies have control -- whether the state has control over the documents of certain agencies. And we heard today for the first time that, you know, there are some hospitals that where they may not have control. So, you know, if the state is willing to engage with us on that topic, we can certainly work with them to limit which agencies they actually have control over and limit the request to getting documents from those agencies.

THE COURT: Well, but your argument is based on the regulations, right? I mean, you don't care what their relationship is outside of those regulations?

MS. SHETH: That is true. And it was our understanding that those hospitals that we had identified were state hospitals. But if we are now hearing that those are actually private hospitals and are not involved in the administration of the Medicaid program, then we accept those representations.

THE COURT: Okay. Thank you.

MS. SHETH: Thank you, your Honor.

THE COURT: Mr. Yu, one last shot.

MR. YU: Yes, your Honor. Bear with me, your Honor,

just very briefly. I mean, there are just a few things Ms. Sheth brought up that were not mentioned previously.

First, the government subpoenas to additional pharmacies, so just to be clear. So the complaint the government refers to five specific pharmacies that were investigated as part of the investigation. The government as part of the Myfortic case, relationship between the other pharmacies which were not, by virtue of the limitation of the seal period, the government didn't have a chance to investigate as carefully. And what we are asking for those communications, those are the very recommendations that we -- are the core of the, what we -- what may be the kickback violation, if a pharmacy was sending communications to a prescriber in the Myfortic case telling prescriber to switch patients, having prescribers switch patients from CellCept, generic to Myfortic. That is a recommendation that we believe gave rise to antikickback statute -- that gives rise to an antikickback statute violation and, therefore, there is absolutely nothing inconsistent between seeking those types of communications and the position the government is taking in this case about relevance.

I mean, as far as, you know, Ms. Sheth also mentioned concept of wilfulness or this aspect of wilfulness under the antikickback statute. Just very briefly, your Honor. You know, Novartis position seems to be that somehow the

government -- what the government which itself is not subject to antikickback statute, may have done which Novartis didn't know about somehow could retroactively render Novartis's belief or its conduct reasonable. I mean, even though the -- in that regard, even though the Prabhu case, which is doesn't involve the antikickback statute, but does involve a fraud claim and does -- is very much on point, basically says you cannot as a defendant or a defendant cannot try to manufacture reasonable belief or try to manufacture ambiguity after the fact. And so given that Novartis didn't know, doesn't claim to be basing its conduct on what the government did, and given that in any event the government itself is not subject to this statute, for Novartis to assert that somehow what the government did or may be doing is relevant to the reasonableness of this conduct, that we simply disagree with.

And in terms of what the government would need to prove at trial, your Honor, again, just to reiterate we don't believe that -- or rather our case is not about medical appropriateness or medical necessity, so that's not part of the Government's burden at trial. But ultimately there will need to be some amount of medical or clinical information simply by way of waive background or to show that the inducement relationship occurred as sufficient to give rise to a kickback liability. But that's a very different proposition from saying that the government has to prove any specific instance or more

generally what happened was factually or objectively inappropriate.

If the Court has no further questions?

THE COURT: Thank you.

Do the states rest?

MR. MILLER: I think we do, your Honor.

THE COURT: Thank you all. It's been very helpful.

MS. SHETH: Thank you, your Honor.

MR. YU: Thank you, your Honor.

(Adjourned)